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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/841,325	04/24/2001	Mark Modell	MDS-009CN (6219/15)	6590
51414	7590	03/21/2005	EXAMINER	
GOODWIN PROCTER LLP PATENT ADMINISTRATOR 53 STATE PLACE EXCHANGE PLACE BOSTON, MA 02109-2881			SMITH, RUTH S	
			ART UNIT	PAPER NUMBER
			3737	
DATE MAILED: 03/21/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 09/841,325	Applicant(s) MODELL ET AL.	
	Examiner Ruth S. Smith	Art Unit 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 December 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 105-111, 113, 115-126, 148 and 150-169 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 105-111, 113, 115-126, 148 and 150-169 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Claim Rejections - 35 USC § 112

Claims 105-111,113,115-126,148,150-169 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification, as originally filed, fails to disclose a pulse rate greater than 25 pulses per second.

Claim Objections

Claims 151,157-158 are objected to because of the following informalities: In claim 151, it is unclear as to how an electromechanical shutter is part of a Markush grouping of materials. It is unclear as to what further structural limitation has been set forth in claims 157,158. The claims are apparatus claims but merely set forth an intended use of the apparatus. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 105-111,113,118,120-125,148,150,152-158,161-166,168 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeBaryshe et al. DeBaryshe et al disclose an optical system for analyzing tissue including means for illuminating and collecting optical radiation in a substantially confocal configuration. The illuminating means and detecting means includes arrays and moveable mirrors and field stops as set forth in the claims. The system can analyze cervical tissue. DeBaryshe et al disclose a pulse rate of 25 pulses per second. In the absence of any showing of criticality or unexpected results the selection of a pulse rate of 25 pulses per second or

one greater than 25 pulses per second would have been obvious in that a pulse rate of 25.001 pulses per second which is greater than 25 pulses per second is a difference in degree rather than kind and would therefore have been obvious to one skilled in the art.

Claims 105-107, 109, 110, 115, 120, 125, 126, 150, 152-162, 165-167 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zavislan ('852). Zavislan discloses an optical system for diagnosing tissue using a confocal illuminating and detecting arrangement. Zavislan discloses an optical system for diagnosing tissue using a confocal illuminating and detecting arrangement. The sheath can comprises the elements shown in figures 9-11 which prevent the imager 83 from contacting the tissue. The sheath is capable of being used only a single time and can be disposed of. The imager used in the apparatus of Zavislan is disclosed as that of US Patent No. 5,788,639 which includes beam splitters/mirrors which are moveable with respect to the patient. Zavislan et al disclose that cervical tissue can be examined. It is well known to access the cervical tissue using equipment such as an endoscope, laproscope etc in order to provide a non-invasive type of device. The use of such would prevent additional harm from coming to the patient by avoiding surgical intervention and would therefore have been obvious to one skilled in the art. In the absence of any showing of criticality or unexpected results the specific pulse rate selected for the scanned illumination would have been an obvious design choice of known equivalents in the art. Furthermore, it would have been obvious to one skilled in the art that the apparatus of Zavislan would have been applicable to any tissue type. With respect to claims 121, 162, the specific field stop dimension used would have been an obvious design choice of known equivalents in the art. Having the tissue not be surgically exposed does not add patentable weight to the apparatus claims.

Claims 108, 111, 113, 118, 119, 123, 148, 168 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zavislan et al ('852) as applied to claims 105, 107, 161 above, and further in view of Kittrell et al. Zavislan discloses an optical system for

diagnosing tissue using a confocal illuminating and detecting arrangement. Zavislan fails to disclose comparing the data obtained to a standard and the use of moveable mirrors to scan the tissue. It is well known in the medical art to obtain data from a tissue region and compare the data to at least one standard in order to properly diagnose the tissue region being tested. An example of such is seen in Kittrell et al. Kittrell et al disclose a method of optically analyzing tissue. Kittrell et al disclose illuminating the tissue using an optical assembly comprising moveable mirrors to focus the light on different regions of tissue. The structure set forth in claim 118,119 is seen in figure 23, elements 68,70. It would have been obvious to one skilled in the art to have further modified Zavislan such that the data obtained is analyzed by comparing such to a known standard in order to provide a diagnosis of the tissue being tested. Furthermore, it would have been obvious to have scanned the tissue sample by using moveable mirrors rather than mechanically translating the imager. Such a modification involves the substitution of one known type of scanning means for another. With respect to claim 121 and 162, the specific field stop dimension used would have been an obvious design choice of known equivalents in the art.

Claims 116,117,122,124,163,164 rejected under 35 U.S.C. 103(a) as being unpatentable over Zavislan ('852) in view of Kittrell et al as applied to claims 108, 152 above, and further in view of Raz. Raz discloses a confocal imaging system which uses an array of emitters and detectors in order to scan a large region of interest. It would have been obvious to one skilled in the art to have further modified Zavislan such that an array of detectors is used in order to scan a larger region of interest in a short time period. Inasmuch as Zavislan discloses the use of optical devices, the array of detectors would require the use of optical elements and processors. The use of an array of detectors and emitters would result in an array of field stops.

Allowable Subject Matter

Claims 151,169 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments filed December 23, 2004 have been fully considered but they are not persuasive. Applicant fails to disclose the criticality of the pulse rate selected. Furthermore, applicant fails to show where the specification as originally filed provides support for such a pulse rate.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth S Smith whose telephone number is (703) 308-3063. The examiner can normally be reached on M-F 5:30 AM- 2:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (703) 308-3552. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Ruth S Smith
Primary Examiner
Art Unit 3737

RSS